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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,715	06/18/2001	Mark Pines	CGD-004.0P-U	7532

7590 11/12/2003

JANE T. GUNNISON, ESQ.  
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NEW YORK, NY 10020

EXAMINER

KWON, BRIAN YONG S

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 11/12/2003

21

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/762,715

Applicant(s)

PINES ET AL.

Examiner

Brian S Kwon

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07/24/2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 24-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Withdrawal of Finality of the Last Office Action***

1. In Examiner's opinion and also in view of a telephonic interview on October 17, 2003, applicants Amendment and Response filed July 24, 2003 appears to be in response to a miscommunication during telephonic interview with Jane Gunnison on July 23, 2003.

During a July 23, 2003 telephone interview, the applicants representative inquired about the clarification on errors in page 2 and 4 of the January 24, 2003, and the examiner stated that No. III on p. 2 of the Office Action should have indicated that the rejection of those claims under 35 USC 102(b) was maintained and the rejection under 103 set forth on pages 3-4 of the Action should be deleted. The examiner indicated that the examiner maintained the original rejection in the Office Action mailed on May 07, 2002. Furthermore, the Examiner indicated that the Supplemental Office Action would be issued with withdrawal of finality of the January 24, 2003 Office Action in case the applicants representative desired to receive the written statement of correcting inadvertent errors on January 24, 2003 Office Action.

On October 17, 2003, the examiner initiated a telephone call to discuss above forgoing matters with the applicants representative, Jane Gunnison, and the agreement was reached to withdraw the finality of the January 24, 2003 Office Action. In addition, the agreement was reached to enter the proposed amendment filed July 24, 2003 and make this Office Action as the Final Office Action since the amendment necessitates the new ground of the rejection.

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***Status of Application***

2. By the amendment filed July 24, 2003, Claims 17-18, 20-21 and 23 have been cancelled and Claims 24-27 have been newly added. Claims 24-27 are currently pending for prosecution on the merits.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 24-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It appears in view of the instant specification and the described mode of action of halofuginone that halofuginone should be administered to a subject (page 41, lines 26-31). However, applicants omitting such essential feature (e.g., who is the recipient of the claimed invention) in independent claims 24 and 26 makes the claimed subject matter vague and unclear and leaves the reader in doubt as to the meaning of the invention to which they refer, thereby rendering the definition of the subject-matter of said claims unclear.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Pines et al. (US 5449678 A).

The claims read on (i) a method of inhibiting a pathological increase in collagen volume in heart tissue, comprising administering a compound having a formula, namely halofuginone (claims 24-25); and (ii) a method of inhibiting the expression of collagen alpha1(I) mRNA in heart tissue, comprising administering a compound having a formula, namely halofuginone (claims 26-27).

Pines'678 teaches the use of quinazolinone containing composition (e.g., halofuginone) for treating or preventing fibrotic disorders such as myocardial fibrosis by inhibiting collagen type I synthesis (col. 6, line 4). The reference also teaches that halofuginone inhibits collagen type I synthesis at transcription level, regardless of the tissue or animal species (column 22, lines 23-26).

Although Pine'678 is silent about the claimed underlying pharmacological mechanism of halofuginone in inhibiting a pathological increase in collagen volume in heart tissue and the expression of collagen alpha1 (I) mRNA in heart tissue, such properties or characteristics must be inherently presented in the prior art method. Since the instant claimed method encompasses prophylactic or protective utility of halofuginone in inhibiting the claimed condition, the prior art method of administering the same compound to a subject would inherently possess such protective use. Therefore, the reference anticipates the claimed invention.

## Conclusion

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5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703) 308-5377. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

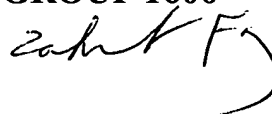
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Brian Kwon

**ZOHREH FAY**  
**PRIMARY EXAMINER**  
**GROUP 1600**

A handwritten signature in black ink, appearing to read "Zohreh Fay", written below the printed name.